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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,456	01/09/2004	Kary B. Mullis	13139-0104 (13721.105006)	7994
20786	7590	12/12/2008	EXAMINER	
KING & SPALDING LLP 1180 PEACHTREE STREET ATLANTA, GA 30309-3521			SAUNDERS, DAVID A	
			ART UNIT	PAPER NUMBER
			1644	
			MAIL DATE	DELIVERY MODE
			12/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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AMENDMENT ENTRY

Amendment of 8/5/08 has been entered. Claims 1-4,7,13-18,22-32 and 34-42 are pending. Claims 32 and 34-42 are under examination.

The presentation of new claims 37-42 has raised further issues with respect to the elected product claims. Also, the examiner has newly considered intervening prior art against the claims in the instant CIP application. Therefore, non-elected method claims 1-4, 7, 13-18 and 22-31 have not been rejoined.

OBJECTION(S)/REJECTION(S) OF RECORD WITHDRAWN

The amendment has overcome previously stated issues as follows:

The objections to claim(s) 32-33 under 37 CFR 1.75.

The rejection of claim(s) 34 under 35 USC 112, 2nd paragraph.

The rejection of claim(s) 34 under 35 USC 112, 1st paragraph.

MAINTAINED DOUBLE PATENTING REJECTION

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 32, 35, 37 and 41-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 7, 33-34 and 36-38 of copending Application No. 11/606,564. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to immunity linker molecules that have both first and second binding sites which are aptamers. The copending claims are broader in terms of the nature of the first site; however, the copending claims clearly encompass the case in which both the first and second binding sites are aptamers (e.g. claim 2, which recites that the immunity linker molecule comprises "a nucleic acid", which would in turn encompass an aptamer).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's response of 8/5/08 has not provided a disclaimer.

NEW REJECTION(S) UNDER 35 USC 112, SECOND PARAGRAPH

Claims 34 and 38-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 depends from cancelled claim 33.

Claims 38 and 39 each fail to state whether the "one binding site" and the "binding sites", respectively, refer to the "first" or to the "second binding site" of base claim 32. It also appears that applicant may have intended that claim 39 would depend from claim 38.

NEW REJECTION(S) UNDER 35 USC 112, FIRST PARAGRAPH

Claim 37 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 37 contains new matter.

Specifically, the original disclosure lacks support for the recitation of "drugs" as a Markush group member. While "drugs" were recited in application PCT/US00/35179 (e.g. p 8), they are not recited in the instant disclosure. The instant disclosure does not incorporate any of the parent applications by reference. Therefore applicant has relinquished his basis for presently reciting "drugs".

NEW REJECTION(S) UNDER 35 USC 102/103

Upon reconsideration the following prior art rejection is newly stated.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32, 35, 37, 39 and 41-42 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mullis (WO 01/45734, cited on PTO-892).

WO 01/45734 is the publication of International application PCT/US00/35179, to which applicant claims priority. In this basis of rejection, the publication is considered to be an intervening reference against the claims of the instant CIP application. The fact situation follows that of *In re Ruscetta* 118 USPQ 101 (see MPEP 201.11).

WO 01/45734 teaches all aspects recited in instant claim 32. The only question to be resolved is whether the phrase "a pre-existing immune response component" (instant claim 32, lines 4-5) encompasses more embodiments than can be supported by the description of International application PCT/US00/35179, to which applicant claims priority. If so, then publication WO 01/45734 can be properly cited as an intervening reference. It is the Office position that the phrase "a pre-existing immune response component" encompasses more embodiments than can be supported by the description of International application PCT/US00/35179. Specifically, the teachings of instant specification pages 7-8 indicate that the phrase "a pre-existing immune response component" encompasses an embodiment in which the immune response component can be one of an "innate immune response". See particularly spec. page 7, lines 15-19. Note, also, that the teachings that "[t]he immune response component is one that exists in the individual prior to administration of the immunity linker to the individual" (spec. page 8, lines 8-10) is consistent with the teachings of an "innate immune response" component at page 7, lines 18-19 (note that any "innate immune response" component is inherently "pre-existing"). Instant claim 32 is thus reasonably interpreted as broadly encompassing an embodiment in which the "pre-existing immune response component" can be an "innate immune response" component.

International application PCT/US00/35179, published as WO 01/45734, lacks any hint that a “pre-existing immune response component” could be an “innate immune response” component; to the contrary, all taught embodiments therein refer to either a B-cell/humoral or a T-cell/cellular immune response component. Thus applicant's earlier filed International application PCT/US00/35179 can only support embodiments of instant claim 32 in which the “a pre-existing immune response component” (lines 4-5) is either a B-cell/humoral or a T-cell/cellular immune response component. Since International application PCT/US00/35179, to which applicant claims priority, cannot support the full scope of instant claim 32, the WO 01/45734 publication is properly considered to be an intervening reference in accord with *In re Ruscetta* 118 USPQ 101.

Since claim 32 can be rejected over WO 01/45734, dependent claims 35, 37, 39 and 41-42 be rejected, since they also embody the case in which the “pre-existing immune response component” can be an “innate immune response” component.

For instant claim 37, note WO 01/45734 at page 8, lines 27-29.

For instant claim 41, note WO 01/45734 at page 7, line 17.

For instant claim 42, note WO 01/45734 at page 8, line 19.

From the above, instant claims 32, 37 and 41-42 are anticipated.

With respect to instant claims 35 and 39 note that WO 01/45734 teaches that “the immunity linker molecule can have more than one binding site to a single substance” (p 8, lines 4-5). One of skill would have expected that different binding sites would “differ in specificity and affinity for binding sites on the target” because the different aptamers directed against a target substance would reasonably be expected to each have a unique binding specificity and affinity. Thus instant claims 35 and 39 would have been obvious from the teachings of WO 01/45734.

To overcome this rejection, applicant must limit claim 32 to the cases in which the phrase “a pre-existing immune response component” (instant claim 32, lines 4-5) is limited to either a B-cell/humoral or a T-cell/cellular immune response component.

CONTACTS

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, can be reached on 571-272-0878. The fax phone number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 12/4/08 DAS

/David A Saunders/

Primary Examiner, Art Unit 1644